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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/913,139 02/09/98 ZENTGRAF H 8484-029-999

<input type="checkbox"/>	HM12/0427	<input type="checkbox"/>	EXAMINER
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NEW YORK NY 10036-2711

NOLAN, P
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ART UNIT	PAPER NUMBER
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1644 21

DATE MAILED: 04/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/913,139</b>	Applicant(s) <b>Zentgraf et al.</b>
Examiner <b>Patrick Nolan</b>	Art Unit <b>1644</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Mar 30, 2001.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) 5-10 is/are withdrawn from consideration.
- 5)  Claim(s) 4 is/are allowed.
- 6)  Claim(s) 1-3 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

**Part III DETAILED ACTION**

1. This application is a 371 of PCT/DE96/00369.
2. Claims 5-10 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected in
3. The finality of the rejection of the last Office action is withdrawn, a new grounds of rejections are set forth below.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by Randall et al. (U<sub>1</sub>).

Randall et al., teaches a polyclonal antibody that specifically binds a histidine portion of a fusion protein, wherein said histidine portion has six histidine residues (see abstract, pages 1250-1251 and Figure 5, in particular).

The prior art teachings anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the

examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 and 3 are rejected under 35 U.S.C. § 103 as being unpatentable over Randall et al., (U1), in view of Sevier (W), of record and Evans et al (AE on the IDS).

Randall et al., has been discussed *supra*. In addition Randall et al., teaches that the polyclonal antibodies which bind the six histidine residues containing tag also bound the p17, rT and Pk epitopes found in the fusion protein.

The claimed invention in claim 3 differs from the prior art teachings only by the recitation of a monoclonal antibody which binds the histidine tagged fusion protein. However, Sevier et al. (Clin Chem. 27: 1797-1806, 1981), teaches the making of monoclonal antibodies from known antigens (pg 1797, column 2, in particular) and that monoclonal antibodies are more homogenous, specific and more easily available than polyclonal antibodies (abstract, in particular). Evans et al., teaches that antibodies to metal binding peptides are useful in immunodetection methods of mbp containing fusion proteins.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the six histidine residue containing tag taught by Randall et al., in the method taught by Sevier et al., to produce monoclonal antibodies that bind six histidine residue containing tagged fusion proteins with the expectation that monoclonal antibodies as taught by Sevier et al., are more specific, homogenous and more easily available than polyclonal antibodies and that said monoclonal antibodies would be useful in immunodetection methods of fusion proteins containing mbp (i.e. the six histidine residue containing tag taught by Randall et al., is a metal binding peptide) as taught by Evans et al.

5. Applicant is notified claim 4 is allowable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any

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inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

*Patrick J. Nolan*

Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
April 26, 2001